



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2013-0093]

Availability of an Environmental Assessment for Issuance of a Permit for Distribution and Sale of an Infectious Hematopoietic Necrosis Virus Vaccine, DNA

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment concerning authorization to import under permit, for distribution and sale, an Infectious Hematopoietic Necrosis Virus Vaccine, DNA. The environmental assessment, which is based on a risk analysis prepared to assess the risks associated with the use of this vaccine, examines the potential effects that this veterinary vaccine could have on the quality of the human environment. Based on the risk analysis and other relevant data, we have reached a preliminary determination that use of this veterinary vaccine will not have a significant impact on the quality of the human environment and that an environmental impact statement need not be prepared. We intend to authorize shipment of this vaccine under permit for distribution and sale in the United States following the close of the comment period for this notice unless new substantial issues bearing on the effects of this action are brought to our attention and provided the product meets all requirements for approval.

DATES: We will consider all comments that we receive on or before [Insert date 30 days after publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0093-0001>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2013-0093, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0093> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1231; phone (301) 851-3426, fax (301) 734-4314.

For information regarding the environmental assessment or the risk analysis, or to request a copy of the environmental assessment (as well as the risk analysis with confidential business information removed), contact Dr. Patricia L. Foley, Risk Manager, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; phone (515) 337-6100, fax (515) 337-6120.

SUPPLEMENTARY INFORMATION:

Under the Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.), a veterinary biological product must be shown to be pure, safe, potent, and efficacious before a veterinary biological

product license may be issued. Prior to importing an unlicensed product, an applicant must obtain approval from the Animal and Plant Health Inspection Service (APHIS) to ship the product under permit for distribution and sale.

To determine whether to authorize shipment and approval for the use of the imported product referenced in this notice, APHIS has considered the potential effects of this product on the safety of animals, public health, and the environment. Using a risk analysis and other relevant data, APHIS has prepared an environmental assessment (EA) concerning the use of the following imported veterinary biological product:

Requester: Novartis Animal Health US, Inc.

Product: Infectious Hematopoietic Necrosis Virus Vaccine, DNA.

The above-mentioned product is a replication-incompetent DNA vaccine consisting of a plasmid vector with an inserted immunogenic gene. The vaccine is intended for the immunization of salmonids as an aid in the prevention of disease due to infectious hematopoietic necrosis virus.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Unless substantial issues with adverse environmental impacts are raised in response to this notice, APHIS intends to issue a finding of no significant impact based on the EA and authorize shipment of the above product for distribution and sale following the close of the comment period for this notice, provided the product meets all other requirements for approval.

Authority: 21 U.S.C. 151-159.

Done in Washington, DC, this 20th day of December 2013 .

Kevin Shea

Administrator, Animal and Plant Health Inspection Service.

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